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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/057,323

01/25/2002

Harry R. Davis

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

09/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/057,323	Applicant(s) DAVIS ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32 and 102-126 is/are pending in the application.
- 4a) Of the above claim(s) 105, 109 and 113-125 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 32, 102-104, 106-108, 110-112 and 126 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicant's response filed July 8, 2008 has been entered.

Claims 32 and 102-126 are pending in the instant application. Claims 105, 109, and 113-125 have been withdrawn as being directed to non-elected species.

Claims 32, 102-104, 106-108, 110-112, and 126 are examined insofar as they read on the elected specie.

The outstanding double patenting rejection is withdrawn in view of the terminal disclaimer filed July 8, 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32, 102-104, 106-108, 110-112, and 126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblum et al. (US Patent 5,846,966), Medical Letter (The Medical Letter on Drugs and Therapeutics, 1998, 40;1030:68-69), references of record, and EP 0 457 514 ('514).

Rosenblum et al. also teaches the elected compound herein, ezetimibe, useful for reducing cholesterol and the risk of arteriosclerosis (See the abstract, also col. 32, Example 6, Compound 6A, and col. 40, line 52 particularly).

Medical Letter teaches fenofibrate as useful in reducing serum cholesterol level (See page 68 – 69).

'514 teaches captopril significantly reduce serum cholesterol in hypercholesterolemic patients and being beneficial as anti-atherosclerotic agents to slow or regress the progress of atherosclerosis (See page 2, lines 17-20, 30-40 for example). '514 also teaches the combination of captopril with an additional cholesterol lowering agent such as HMG-CoA reductase inhibitors (See the abstract and claims 1-3 for example).

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The references do not expressly teach a composition containing fenofibrate and ezetimibe, and captopril together.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate ezetimibe, fenofibrate, and captopril together in a single composition.

One of ordinary skill in the art would have been motivated to incorporate both ezetimibe, fenofibrate, and captopril together in a single composition. The prior art teaches that ezetimibe, fenofibrate, and captopril as useful in reducing cholesterol and reduce the risk of atherosclerosis individually. Therefore, combining two or more agents, which are known to be useful to reduce cholesterol and reduce the risk of atherosclerosis individually, into a single composition useful for the very same purpose is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069). Furthermore, the examiner notes that captopril is known to be useful in combination with cholesterol lowering agents as disclosed in '514. Therefore, possessing the teachings of the cited prior art, one of ordinary skill in the art would have been motivated to incorporate the herein claimed actives together in a single composition for reducing cholesterol and the risk of atherosclerosis.

Response to Arguments

Applicant's arguments filed July 8, 2008 averring the cited prior art's failure to teach the herein claimed actives have same mechanism of actions have been fully considered but they are not persuasive. The examiner notes that the basis of the

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rejection resides on the fact that the herein claimed actives are all well-known individually to be useful in reducing cholesterol and the risk of atherosclerosis.

Therefore, it flows logically to combine these agents into a single composition useful for the very same purpose, absent evidence to the contrary (See *Kerkhoven supra*).

Therefore, even though the mechanism of ezetimibe may not be fully understood at the time of filing, it is known to be useful in reducing cholesterol; therefore, combining the herein claimed actives into a single composition would be obvious as discussed above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617

/San-ming Hui/
Primary Examiner, Art Unit 1617